In the United States Court of Federal Claims
OFFICE OF SPECIAL MASTERS
No. 13-956V

LEILAH AL-UFFI, *on behalf of her minor child,* R.B.,	*	Special Master Corcoran
Petitioner,	*	Filed: February 22, 2017
v.	*	Keywords: Human Papillomavirus ("HPV"); Anti-NMDA Receptor Encephalitis; Onset.
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Andrew Donald Downing, Van Cott & Talamante PLLC, Phoenix, AZ, for Petitioner.

Debra A. Filteau Begley, U.S. Dep't of Justice, Washington, DC, for Respondent.

RULING ON ENTITLEMENT[1]

On December 5, 2013, Leilah Al-Uffi filed this action seeking compensation under the National Vaccine Injury Compensation Program (the "Vaccine Program")[2] on behalf of her minor child, R.B. Ms. Al-Uffi alleges that R.B. suffered from an autoimmune encephalopathic event, anti-NMDA (N-methyl D-aspartate) receptor encephalitis ("ARE"), as a result of receiving the human papillomavirus ("HPV") vaccine on December 8, 2010. Petition ("Pet.") (ECF No. 1) at 2.

Although this case had originally been set for hearing, the parties requested that the matter be taken off the trial calendar, and instead that Petitioner's claim be resolved via a ruling on the

[1] This decision will be posted on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 (2012). As provided by 42 U.S.C § 300aa-12(d)(4)(B), however, the parties may object to the decision's inclusion of certain kinds of confidential information. To do so, Vaccine Rule 18(b) permits each party fourteen (14) days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the decision in its present form will be available to the public. *Id.*

[2] The National Vaccine Injury Compensation Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755 (codified as amended at 42 U.S.C. § 300aa-10 through 34 (2012)). References to the Vaccine Act herein shall omit the statutory prefix.

record. *See* Petitioner's Motion for Judgment on the Administrative Record, filed on August 18, 2016 (ECF No. 65) ("Mot."). After considering the record as a whole, and for the reasons explained below, I find that Petitioner has carried her burden establishing causation, and therefore has demonstrated entitlement to compensation under the Vaccine Program.

I. FACTUAL BACKGROUND

A. R.B.'s Initial Medical History and HPV Vaccinations

R.B. was born on February 27, 1998. She experienced no major childhood health problems in her ensuing years, with the exception of alopecia areata occurring at the age of nine, seasonal allergies, and occasionally strep throat. *See* Petitioner's Exhibit ("Pet'r's Ex.") 6 at 52 (ECF No. 12). On June 4, 2010, R.B. was seen for her 12-year-old well child checkup, and at that time received the Tetanus-diphtheria-acellular-pertussis ("Tdap"), Varivax (dose 2), and HPV vaccines. *Id*. at 32. R.B. was noted to be "generally healthy" with no concerns listed by her mom, and was to return in two months for the second HPV dose. *Id*. 32-34.

Two months later, on August 6, 2010, R.B. received that second dose, and was instructed to return in four months for the third and final vaccine in the series. She did so on December 8, 2010. Pet'r's Ex. 6 at 36. The records suggest that this was merely a nurse's visit, and therefore there was no medical examination performed on her at that time.

B. Petitioner's Counseling Before Vaccination

R.B.'s medical history includes records of some pre-vaccination behavioral/psychological counseling that is relevant to her claim. On July 12, 2010, R.B. was seen by a school counselor, Becky Yankovich, LPC, MS[3] to address numerous instances, dating back to March 2010, in which she had displayed behavioral difficulties. Pet'r's Ex. 21 at 9. As Ms. Al-Uffi informed the counselor, R.B. had trouble adjusting to middle school. *Id*. The main concerns for R.B. were her cutting herself, daily disagreements with Ms. Al-Uffi, and problematic contact with boys. *Id*. at 6. R.B.'s living situation was a particular point of conflict. R.B. lived with Petitioner during the week, but spent the weekends with her grandmother, who (in Petitioner's words) was "inappropriately smothering" R.B. *Id*. R.B. had also expressed the desire to move to her father's house so she could

[3] LPC is an abbreviation for licensed professional counselor, while MS is an abbreviation meaning Master of Science. *See Mental Health Providers: Tips on Finding One*, Mayo Clinic (Feb. 18, 2014), http://www.mayoclinic.org/diseases-conditions/mental-illness/in-depth/mental-health-providers/art-20045530, last visited (Dec. 9, 2016).

live with her half-brothers and sisters. *Id*. The July 2010 counseling visit concluded with a diagnosis of Adjustment Disorder with Mixed Disturbance of Emotions and Conduct.[4]

R.B. obtained additional counseling from Ms. Yankovich on December 1, 2010. *Id*. at 1. Based upon the filed record, this session appears to have been intended to address R.B.'s behavior related to recent bullying at school and R.B's texting of inappropriate pictures to a boy. *Id*. Outside of those issues, R.B. was noted to be oriented, with a present affect. *Id*. There is otherwise no reference in these pre-vaccination mental health records to any kinds of more alarming behaviors possibly reflective of neurologic injury of the sort alleged to have occurred in this case after administration of the third dose of the HPV vaccine.

C. Post-Vaccination Efforts to Treat R.B.'s Mental Health Symptoms

The immediate post-vaccination medical records are not, taken as a whole, a model of clarity. It appears that some records relevant to the treatment R.B. received in the days after December 8, 2010, could not be located or were not filed, despite the parties' efforts to obtain them, making it difficult to ascertain the precise timeline of events. Moreover, statements about the onset of certain of R.B.'s symptoms are inconsistent, and to some extent seem to reflect the overlapping types of care that Petitioner sought for R.B. in this time period. The contemporaneous records also do not contain recitation of some of the more alarming or novel symptoms that subsequent records assert R.B. was then experiencing. Nevertheless, close examination of the filed records does reveal some common themes or agreed-upon facts.

In the days immediately following the administration of the third HPV vaccine dose, Ms. Al-Uffi became concerned enough about R.B.'s mental state to seek treatment from a number of mental healthcare providers. Thus, on December 10, 2010, R.B. was seen at Parkside Psychiatric Hospital ("Parkside") in Tulsa, Oklahoma. Pet'r's Ex. 22 at 1. Although the records from this visit record the fact that R.B. had been displaying inappropriate or concerning behaviors in the previous months, "*in the past 24 hours* she is very tired, not eating, shuts down, won't talk." *Id*. (emphasis added). The assessment also noted that R.B. had very recently struck her grandmother the first weekend of December, although R.B. explained this as a reaction to her grandmother grabbing her by the arm and stressed that she had apologized for it. *Id.* Petitioner also stated that R.B. would become nonresponsive and glassy-eyed when attempts were made to discuss R.B.'s behavior, but it appears from the context of the record in which this was discussed that R.B. was mainly being oppositional rather than displaying some kind of more severe neurologic symptom. *Id*. at 2. This

[4] An adjustment disorder is "a maladaptive reaction to identifiable stressful life events, such as divorce, loss of job, physical illness, or natural disaster; this diagnosis assumes that the condition will remit when the stress ceases or when the patient adapts to the situation." *Dorland's Medical Dictionary* 547 (32nd ed. 2012) (hereinafter "*Dorland's*").

particular treatment record contains no other mention of any more recent, post-vaccination behaviors different from what R.B. had displayed in the past.

R.B. was not admitted to Parkside because she did not pose a suicide risk. Pet'r's Ex. 21 at 3. The medical record also contains reference to a visit on the same date (December 10, 2010) to a different mental health care provider, Shadow Mountain Behavioral Health System, but no record of that visit was ever filed.[5] Pet'r's Ex. 21 at 3. It also appears (based upon references from R.B.'s subsequent medical treatment history) that R.B. visited the Saint Francis Hospital Emergency Room on December 11, 2010, in connection with Ms. Al-Uffi's concerns about more alarming changes in R.B.'s behavior. *See e.g.,* Pet'r's Ex. 4 at 24, 26, and 32, Pet'r's Ex. 7 at 58, 67, 74, 534, 530, and 569.[6]

The next record evidence of Ms. Al-Uffi's attempts to treat R.B.'s change in mental status is from a December 13, 2010, return visit to R.B's counselor, Ms. Yankovich. Progress notes from that visit state that R.B. was not oriented to place or date, specifically representing that R.B. "seems to have had a seizure - does not make sense when talking, unable to communicate" since Wednesday (December 8, 2010). The visit concluded with a recommendation that Petitioner bring R.B. to the emergency room. Pet'r's Ex. 21 at 3.

D. Diagnosis of ARE

After the return visit to Ms. Yankovich, R.B. was taken to the Saint Francis Emergency Room ("ER") in Tulsa and admitted to the hospital later that afternoon. *See generally* Pet'r's Exs. 4 and 7. The initial assessment from the ER record noted that R.B.'s mother had informed treaters that R.B's symptoms had begun the Wednesday prior, on December 8, 2010 (the date of the final HPV vaccination), and that in the following days R.B. had experienced episodes of slurred speech, smacking lips, speaking Spanish (a language she was studying in school but which was not spoken at her home), and dancing spontaneously. Pet'r's Ex. 7 at 530, 569. Those records state that "p[atient] has no h/o [history of] a similar episode." *Id.* Ms. Al-Uffi also recalled that R.B. had suffered from an upper respiratory infection ("URI") three weeks prior.[7] *Id.* at 63.

[5] Petitioner's counsel filed the response he received from Shadow Mountain following a subpoena request for the missing records around December 10, 2010. The response only stated that "the above mentioned patient [R.B.] has never been admitted to this facility at the inpatient, nor residential level of care pre nor post April 14, 2012." Pet'r's Ex. 41 at 5.

[6] Despite the numerous references in the medical records to a visit to Saint Francis on December 11, 2010, the Medicaid lien information for R.B. did not record such a visit. Pet'r's Ex. 42 at 2. However, the notes from R.B.'s intake at Saint Francis on December 13, 2010, indicated that R.B.'s glucose levels were tested on December 11, 2010, but came back normal, and that she was not admitted. Pet'r's Ex. 4 at 32.

[7] References to this URI in the record are from reports made by Ms. Al-Uffi. There were no medical records filed in this case that document R.B. seeing a doctor for treatment of that URI.

After her admission, R.B. was evaluated by Dr. David J. Siegler, a neurologist at Saint Francis. Pet'r's Ex. 7 at 63. Dr. Siegler considered possible etiologies for R.B.'s condition, including post-infectious encephalopathy or idiopathic encephalopathy. Pet'r's Ex. 4 at 22. He initially speculated that if R.B. had experienced a post-infectious encephalopathy, it likely had resulted from the prior URI reported by Ms. Al-Uffi, although brain lesions that would have been characteristic of a post-infectious reaction that had injured her neurologically were not observed on an MRI[8], leading him away from that diagnosis. *Id.* Indeed, both the first and second MRIs (performed on R.B. on December 17, 2010) showed no abnormal enhancement[9]. Pet'r's Ex. 7 at 505.

R.B.'s stay at Saint Francis from December 13-29, 2010, included evaluations by several doctors in addition to Dr. Siegler. Drs. Keith Mather and Michael Chang were primarily responsible for the day-to-day monitoring of R.B's condition.[10] Pet'r's Ex. 7 at 67. The first few days after admission focused on ordering testing, including a urine drug screen, CBC, C-reactive protein test, and a lumbar puncture.[11] Pet'r's Ex. 4 at 28. Dr. Chang first reviewed the findings from those tests on December 16, 2010. Like Dr. Siegler, he considered viral and infectious etiologies for R.B.'s condition, but recognized that R.B.'s first MRI did not corroborate that hypothesis. *Id*. at 28. His differential diagnosis also contemplated other infectious etiologies that have been associated with encephalopathy, such as her reported recent URI. *Id.* at 29. He thus ordered further testing to look for the presence of mycoplasma[12] in the cerebrospinal fluid (CSF). *Id*.

---

[8] MRI stands for Magnetic Resonance Imaging. *Dorland's* at 1184.

[9] The radiology report from the second MRI recorded that there was "mild dilation of the lateral ventricles, third ventricle and fourth ventricles" but otherwise the results were normal. Pet'r's Ex. 7 at 335. After reviewing the MRI, however, Dr. Chang noted that there was no abnormal enhancement, concluding that "this makes infectious encephalitis much less likely as this MRI has been obtained 10 days into disease." *Id*. at 505.

[10] R.B.'s medical records indicate that Dr. Mather was her attending physician and Dr. Chang was a consulting physician. Pet'r's Ex. 7 at 67. R.B. also saw Dr. Stephen Groves, an ophthalmologist, and Dr. Kirsten Wilkins, a psychiatrist. *Id*. at 72, 76.

[11] CBC is a complete blood count. The results for R.B. were white blood cell count of 7.6, hemoglobin 14.2, platelets 284, 70% segmented cells, 21% lymphocytes, 8% monocytes, and 1% eosinophils. *Dorland's* at 310, Pet'r's Ex. 4 at 28. C-reactive protein levels are determined by measuring for a C-reactive protein in the blood. *Tests and Procedures: C-reactive Protein Test*, Mayo Clinic, http://www mayoclinic.org/tests-procedures/c-reactive-protein/basics/definition/PRC-20014480 (last visited Feb. 6, 2017). The protein increases if there is inflammation in the body, R.B.'s results did not indicate such inflammation. *Id*.

[12] Dr. Chang was testing for a specific mycoplasma titer (mycoplasma pneumonia), which is often causes unapparent infections or mild respiratory tract disease but can also cause mycoplasmal pneumonia. *Dorland's* at 1217.

Two days later, Dr. Chang reevaluated R.B. He now had the results of her second MRI, which again showed no abnormal enhancement, and further inconclusive CSF results. Pet'r's Ex. 7 at 505. Based on such data, Dr. Chang opined that infectious encephalopathy was unlikely. R.B. did have a positive Streptozyme test, but because her anti-streptolysin O ("ASO") antibody[13] was within the normal range, he concluded that it was unlikely that such an infection had played a role in R.B's condition. *Id*.

On December 21, 2010, Dr. Chang received the results of the mycoplasma titers from R.B.'s blood. The IgG titers were positive, while the IgM titers were negative.[14] Because these results made it difficult to identify how recent the infection had been, Dr. Chang opted to delay initial treatment until he received another test confirming the result. Pet'r's Ex. 7 at 496. That second test produced negative results for both IgG and IgM, leading Dr. Chang to conclude that R.B.'s condition was "unlikely to be related to an identifiable infectious etiology." *Id*. at 489. Dr. Chang's last visit with R.B. before discharge was on December 27, 2010, at which time he recommended that no further infectious testing needed to be performed, and concluded that R.B.'s symptoms had an unclear etiology. *Id*. at 479.

While at Saint Francis, R.B. also underwent a CT scan that showed possible mild prominence of the third and fourth ventricles, and multiple EEGs showing some epileptic activity that began to be controlled by Keppra.[15] Pet'r's Ex. 7 at 33, 335, 338, and 339-42. R.B. was treated with IVIG steroids but did not exhibit meaningful improvement. R.B. remained hospitalized at Saint Francis through December 29, 2010, after which she was moved to a rehabilitation center at the University of Oklahoma Hospital ("UOH"), with a diagnosis of encephalitis and seizures. *Id.* at 56. She was subsequently transferred from UOH to Cook Children's Medical Center ("CMC") on January 5, 2011, after her family noted that R.B. was exhibiting increased agitation and seizure activity. Pet'r's Ex. 2 at 1.

The medical history of R.B.'s treatment from later in December into early 2011 continued to show inconsistent statements regarding the date of onset of her most notable neurologic or behavioral symptoms. Thus, the history recorded at CMC set forth December 6, 2010 – two days

[13] The ASO titer measures antibodies in the blood serum one week to one month after the onset of a streptococcal infection. Pagana, *Mosby's Manual of Diagnostic and Laboratory Tests*, 102 (Fourth Edition 2010). Streptozyme testing is similar to an ASO titer but is more difficult to interpret. Pet'r's Ex. 7 at 505.

[14] A positive IgG result indicates a past or resolved infection, while IgM antibodies indicate an ongoing or very recent infection. Pet'r's Ex. 7 at 326.

[15] Keppra is the brand name of the medication (Levetiracetam) used to help control some types of seizures. *Drugs and Supplements: Levetiracetam (Oral Route)*, Mayo Clinic, http://www.mayoclinic.org/drugs-supplements/levetiracetam-oral-route/description/DRG-20068010 (last visited Dec. 29, 2016).

before vaccination – as the onset, characterized by bizarre behavior, crying, and agitation. Pet'r's Ex. 2 at 1. By contrast, the Saint Francis records indicated that R.B.'s symptoms began with confusion on December 8, 2010 followed by smacking lips, staring spells, and speaking Spanish, leading R.B.'s mother to seek treatment for R.B. on December 10, 2010. Pet'r's Ex. 7 at 530, 569.

A repeat MRI was performed at CMC on January 6, 2011, and now showed mild diffuse cerebral volume loss along with some enlargement of the supratentorial ventricles. Pet'r's Ex. 2 at 22. R.B.'s extensive evaluation at CMC included another infectious disease screen, which produced no new meaningful results suggesting an infectious cause. *Id*. at 52-61. However, CMC also tested R.B. for NMDAR antibodies, which returned a positive result. *Id*. at 69. That, plus her existing corroborative symptoms, resulted in R.B. being formally diagnosed with ARE. *Id*. at 21. Because many patients with ARE often have cancer,[16] R.B. was evaluated by oncology, but no other evidence of a tumor or other cancerous source were identified. *Id*. R.B. was then treated with a five day course of IVIG and steroids and showed dramatic improvement. *Id*.

For the next three years, R.B. saw her treating neurologist from St. Francis, Dr. Siegler, and continued to show steady improvement. Pet'r's Ex. 6 at 120. R.B. also continued to manifest behavioral impulsivity issues, which has created interpersonal tension with Mrs. Al-Uffi, leading Dr. Siegler to recommend further family counseling. *Id*. at 210.

II. EXPERT TESTIMONY

Petitioner has offered expert reports from R.B.'s treating physician, Dr. Siegler, plus an immunologist. Respondent offered the report of an expert in pediatric neuro-immunology. The opinions and testimony of the relevant experts are set forth below.

A. Dr. David J. Siegler

David J. Siegler, M.D., R.B's treating pediatric neurologist, opined that the HPV vaccine had caused her ARE. He offered a single written report in support of this opinion. *See* Expert Narrative Report, filed as Pet'r's Ex. 18 on October 10, 2010 (ECF No. 23-1) ("Siegler Rep."). The first two pages of Dr. Siegler's four-page report detailed R.B's clinical progression, including her current status, with the remaining two pages addressing the research Dr. Siegler performed on the potential connection between the HPV vaccine and ARE. He concluded (despite the limited number of reported cases available and absence of direct evidence linking the HPV vaccine) that R.B.'s case "strongly suggests a correlation to causation for her suffering a vaccine-related injury." Siegler Rep. at 4.

[16] Literature on ARE often reports an association between the condition and ovarian, small cell lung, breast, and GI cancers. Pet'r's Ex. 2 at 12.

Dr. Siegler graduated from the University of Texas Southwestern Medical School, after completing his undergraduate degree at Stanford University. Pet'r's Ex. 19 at 4. Dr. Siegler went on to complete his residencies in Pediatrics (focusing on Child Neurology) at Stanford University Hospital (1992-1993). *Id*. Dr. Siegler is board certified in medicine, psychiatry, and neurology. *Id.* at 2. He is currently with the Department of Pediatrics at the University of Oklahoma College of Medicine and Oklahoma University State College of Osteopathic Medicine as a clinical assistant professor and maintains a clinical practice at a Child Neurology of Tulsa, P.C. *Id*. at 1.

Consistent with the medical records, Dr. Siegler noted that he first saw R.B. on December 13, 2010, for a neurological consultation during R.B.'s hospital stay at Saint Francis Hospital. Pet'r's Ex. 7 at 63. Thus, his opinion is based on his direct knowledge as her treating physician, as well as the medical literature he presented in his narrative report.

Dr. Siegler specifically opined that R.B.'s ARE occurred within sufficient temporal proximity to her receipt of the HPV vaccination to suggest the two were causally connected. Siegler Rep. at 4. In support of his opinion, Dr. Siegler referenced contexts in which different vaccines have been observed to cause an immune response that may become pathologic and thereby cause an autoimmune disease. *Id*. at 3. He specifically cited medical literature reporting the case of a 15 year-old girl diagnosed with ARE after receiving the Tetanus diphtheria acellular pertussis and polio vaccines. *See* Caroline Hofmann, Marc-Oliver Baur, Horst Schroten. *Anti-NMDA receptor encephalitis after TdaP–IPV booster vaccination: cause or coincidence?*, J Neurol. (2011) 258:500–501, filed as Pet'r's Ex. 47 (ECF No. 76) ("Hofmann"). Although the vaccines in Hofmann were different, Dr. Siegler proposed that the brief temporal period between vaccination and onset was comparable to R.B.'s experience. Dr. Siegler's report admitted that he could not identify documented cases of HPV-induced ARE, but proposed that this was attributable either to lack of reporting or lack of testing for the presence of the NMDA antibodies in what would be otherwise relevant cases. Siegler Rep. at 2.

B. Dr. David Axelrod

Petitioner's second expert, David Axelrod, M.D., provided an immunologic opinion for the theoretical causative role the HPV vaccine could play in developing ARE. He filed two reports in this case. *See* Pet'r's Ex. 8, filed August 27, 2014 ("First Axelrod Rep."); Pet'r's Ex. 24, filed on February 6, 2015 ("Second Axelrod Rep.").

Dr. Axelrod graduated from the University of Michigan Medical School in 1974 (after obtaining his bachelor's degree at Michigan as well). Pet'r's Ex. 9 at 1. He completed two residencies in internal medicine, one at the University of Toronto and one at William Beaumont Hospital, followed by additional residencies with a fellowship in allergy, immunology, and rheumatology at McGill University, and then served as a fellow for the National Institutes of

Health in the laboratory of clinical immunology. *Id*. Dr. Axelrod is board certified in medicine, allergy and immunology, adult rheumatology, and medical laboratory immunology. *Id*. He currently works in private practice, with the vast majority of patients having allergies, immunologic conditions, or autoimmune rheumatic diseases. *Id*.

Dr. Axelrod proposed that a secondary immune response—a reaction to a subsequent exposure to the same antigen—could cause ARE, and in this case caused R.B.'s ARE. First Axelrod Rep. at 1. In contrast to a primary immune response that may not peak until two weeks after a vaccine or other antigen exposure, a secondary immune response can begin within a day. *Id*, *see also* Abbas, A.K., *Cellular and Molecular Immunology Edition 6.* 6 ed. 2010, Philadelphia: Saunders Elseier. 566, filed as Pet'r's Ex. 10 (ECF No. 21-3)("Abbas"). The remainder of Dr. Axelrod's First Report applied the primary and secondary elements established by Miller, F.W., et al., *Approaches for identifying and defining environmentally associated rheumatic disorders. Arthritis Rheum*, 2000, 43(2): p. 243-9, filed as Pet'r's Ex. 11 (ECF No. 21-4) ("Miller"), which assess the plausibility that an environmental exposure - here the third dose of the HPV vaccine - causing the appearance of a disease.[17]

Of the eight Miller elements, Dr. Axelrod posited that R.B. met the criteria for four of the primary and one of the secondary elements, which he considered sufficient to establish a causal relationship between the third dose of the HPV vaccine and R.B.'s ARE. First Axelrod Rep. at 2. The first of those elements, Dr. Axelrod opined, was the close temporal association. Onset of R.B.'s most alarming neurologic changes began within two days of vaccination - consistent with a secondary immune response. *Id*. He then briefly stated that the lack of alternative explanations for her condition, the improvements in her symptoms in the month following onset (which he characterized as evidence of "dechallenge[18]"), and the existence of other reported cases of a similar reaction, were conclusive evidence that R.B. met two additional primary elements and

[17] *Miller* established five primary elements and three secondary elements, the presence of four of the elements with at least three being primary elements was evidence of a causal relationship. Miller, F.W., et al., *Approaches for identifying and defining environmentally associated rheumatic disorders*. Arthritis Rheum, 2000. 43(2): p. 243-9. The primary elements are (1) temporal association consistent with known biologic effects, (2) lack of likely alternative explanations, (3) dechallenge - did the defining aspects of the disorder disappear or improve when the exposure was removed, (4) rechallenge - did the disorder reappear or worsen when the exposure was reintroduced, and (5) biologic plausibility-is the disorder plausible based upon the known in vivo or in vitro effects of the exposure. *Id*. The secondary elements are (1) analogy- are there prior published or unpublished reports of a similar disorder developing after the exposure in question or after a similar exposure, (2) dose responsiveness-is there evidence that the dose or extent of the exposure is related to the likelihood of developing the disorder or to the disorder's severity and (3) specificity- are the defining symptoms, signs, and laboratory features of the disorder the same as those seen in previous cases after exposure to the same environmental agent. *Id. Escalera v. Sec'y of Health & Human Servs.,* No. 14-431, 2016 WL 7422308, at *5 (Fed. Cl. Spec. Mstr. Nov. 23, 2016) (finding in favor of Petitioner who relied upon the *Miller* elements to establish causation).

[18] Dechallenge is when the defining aspects of the disorder disappear or improve when the exposure is removed. *Miller* at 243-9.

one secondary element. *Id*. at 3-4.

The last of the elements Dr. Axelrod addressed was the biological possibility that the HPV vaccine could cause inflammation in the brain and ultimately damage brain tissues. First Axelrod Rep. at 3. He relied on the theory that vaccination can elevate production of a variety of cytokines sufficient to breach the blood-brain barrier, thereby allowing the ARE autoantibodies access to brain tissues (and thereby interfere with the NMDA receptors, as is posited occurs in ARE). *Id*. Specifically he cited to Garcia-Pineres, A., et al., *Cytokine and Chemokine Profiles Following Vaccination with Humanpapillomavirus Type 16 L1 Virus-like Particles,* Clin. Vaccine Immunol., 2007. 14(8): p. 984-9 ("Garcia-Pineres") (filed as Pet'r's Ex. 27), which observed that eight different cytokines were significantly upregulated following receipt of the HPV vaccination. Thus, the immune process kicked off by receipt of the HPV vaccine could encourage production of the cytokines necessary, under his theory, to cause, by way of a second mechanism, ARE in the timeframe at issue in this case.

Dr. Axelrod initially proposed the mechanism of molecular mimicry, which he stated could occur after an upregulation of cytokines caused a breach in the blood-brain barrier, allowing the autoantibodies to interact with the brain's NMDA receptors.[19] To this end, Dr. Axelrod cited to Kanduc, D., *Quantifying the Possible Cross-Reactivity Risk of an HPV16 Vaccine*, J Exp. Ther. Oncol., 2009. 8(1): p. 65-76, filed as Pet'r's Ex. 14 (ECF No. 21-7)("Kanduc"), to establish that homology has been found between the Human Papilloma Virus 16 proteome[20] and existing human proteins, thus allowing for the conclusion that an autoimmune disease could occur via the mechanism of molecular mimicry. *Id*. In addition, Dr. Axelrod relied on Ufret-Vincenty, R.L., et al., *In vivo survival of viral antigen-specific T cells that induce experimental autoimmune encephalomyelitis*. J Exp. Med., 1998. 188(9): p. 1725-38, filed as Pet'r's Ex. 15 (ECF No. 21). That article found homologous structures between HPV L2 and myelin basic protein[21] sufficient to theoretically cause the production of antigen-specific T-cells that have been used to induce Experimental Autoimmune Encephalomyelitis in mice. *Id*.

---

[19] Molecular mimicry occurs when there are sufficient structural similarities (homology) between a foreign antigen (such as a vaccine) and a structure that already exists in the body (such as the brain or central nervous system). In some cases, when the foreign antigen encounters the structure already in the body, the body mistakenly attacks the existing structure as foreign, creating an autoimmune process. In order for molecular mimicry to occur, there must first be a disruption in the blood brain barrier. This is typically the first part of the immune response, and is caused by elevated levels of cytokines that increase the permeability of the blood brain barrier. *McCulloch v. Sec'y of Health and Human Services*, No. 09-293, 2015 WL 3640610, at *17 (Fed. Cl. Spec. Mstr. May 22, 2015).

[20] A proteome is the complete set of proteins produced from the information encoded in a genome. *Dorland's* at 1535.

[21] Myelin basic protein is the building-block substance from which is formed the myelin sheath, which coats a nerve's axon. In a demyelinating condition, the myelin is destroyed, producing evidence of myelin basic protein in the blood, and leaving the nerves exposed to potential damage. *Dorland's* at 1218, 486.

Dr. Axelrod's second report primarily addressed factual timing issues rather than substantive portions of Respondent's expert report. *See generally* Second Axelrod Rep. In particular, he sought to bolster his opinion that R.B.'s onset (which he identified as December 10, 2010) was a medically appropriate period from her date of vaccination two days earlier for occurrence of a secondary immune response. *Id.* at 4. Manifestation of symptoms two to five days following vaccination, as he posited occurred here, was in his opinion consistent with a secondary immune response, which would be inherently more rapid. *Id*. He also dismissed Respondent's contention that the lack of research linking the HPV vaccine to ARE meant that there could not possibly be a relation between the two. *Id*.

Dr. Axelrod's Second Report also attempted to rebut Respondent's contention that the homology Petitioner proposed as part of the molecular mimicry mechanism by which the ARE antibodies were produced was not possible, because the Gardasil version of the HPV vaccine R.B. had received did not contain the proteins he had discussed in his first report.[22] Dr. Axelrod now narrowed his focus to the HPV L1 protein and its known homology to ankyrins, the Apolipoprotien-B100 and complement C1q receptor. Second Axelrod Rep. at 5. He also proposed an alternative mechanism – epitope spreading[23] - arguing that R.B.'s immune response to the homologous proteins could have caused damage to her neurons, which in turn could damage adjacent structures, including NMDA receptors. *Id*. He offered no medical literature, however, addressing epitope spreading in the context of the HPV vaccine and ARE. *Id*.

C. Dr. Mark P. Gorman

Respondent's expert, Mark P. Gorman, M.D., opined that the third dose of the HPV vaccine R.B. received neither caused, nor significantly aggravated, R.B.'s ARE.[24] Resp't's Ex. A. at 8. Rather, and based upon his own review of the medical records, R.B's symptoms most likely started either before receiving the vaccine or too soon thereafter to establish the vaccine's role in the

[22] Gardasil is a quadrivalent vaccine "compris[ed] [of] virus-like particles (VLPs) of the major capsid L1 protein of human papilloma virus types 6, 11, 16, and 18." *See* Sutton I, Lahoria R, Tan IL, et al., *CNS demyelination and quadrivalent HPV vaccination*, Multiple Sclerosis. 2009; 15:116, filed as Resp't's Ex. A, Tab 13.

[23] As noted in a different Vaccine Act decision, "[e]pitope spreading is based upon how antibodies interact with antigens after the antibody binds to the antigen. As the body reacts to the antigen, the antibody unravels the coiled strands of proteins that comprise the antigen. This uncoiling exposes other epitopes of the antigen to the body. Because the body has not seen this precise epitope before, the body responds by sending out a new sequence of antibodies." *Tosches ex. rel Tosches v. Sec'y of Health & Human Servs.*, No. 06-192, 2008 WL 440285 at *6 (Fed. Cl. Spec. Mstr. Jan. 31, 2008).

[24] Petitioner has not alleged a claim of significant aggravation. *See e.g.* Mot., Amended Petition. Dr. Gorman nevertheless maintained in his expert reports that it was unlikely that the HPV vaccine could have exacerbated an underlying or subacute ARE in R.B. given the overall mild nature of her encephalitis (at least in comparison to other individuals with the disease). Resp't's Ex. A. at 7.

disease's etiology. *Id.* Like Dr. Axelrod, Dr. Gorman filed two expert reports in total. *See* Resp't's Exs. A, filed December 12, 2014 ("First Gorman Rep."); Resp't's Ex. C, filed September 18, 2015 ("Second Gorman Rep.").

Dr. Gorman completed his medical degree in 2001 from Harvard University Medical School (after obtaining a bachelor's degree at Duke University), performing his residencies in child neurology at Boston Children's Hospital. Resp't's Ex. B. Today, Dr. Gorman directs the Multiple Sclerosis and neuro-immunology program (which he founded) at Boston Children's Hospital, where he sees patients while also serving as an Assistant Professor of Neurology at Harvard Medical School. First Gorman Rep. at 2.

Dr. Gorman's first expert report took particular issue with the assertions made by Petitioner's experts about the timing in which R.B. is alleged to have experienced her post-vaccination ARE. First Gorman Rep. at 2-8. In his opinion, the "fatal flaw" in Petitioner's case was that the records established onset of R.B.'s condition before the third HPV vaccination. *Id*. at 4. He relied heavily on the records from CMC that placed onset on December 6, 2010, along with R.B.'s documented behavioral issues in the summer and fall of 2010, which he suggested were consistent with a preexisting neurologic injury. *Id*. Otherwise, the record suggested onset not long after receipt of the vaccine. Dr. Gorman opined that there were seven steps needed for the biological mechanisms required to result in encephalitis.[25] *Id*. at 5. The minimum amount of time needed between vaccine administration and neurological symptoms would be five days, making R.B.'s onset too soon. *Id*.

Dr. Gorman also pointed to certain test results that he felt suggested onset of R.B.'s ARE predated her December 2010 vaccination. R.B.'s initial CT and second MRI, performed December 17, 2010, both showed a reduction in her brain tissue volume - a feature that can be consistent with ARE. First Gorman Rep. at 7; *see also Dalmau J, Lancaster E, Martinez-Hernandez E, et al. Clinical experience and laboratory investigations in patients with anti-NMDAR encephalitis.* Lancet Neurol. 2011; 10: 63–74, filed as Resp't's Ex. A Tab 2 ("Dalmau"). However, in order to cause such a tissue volume loss, Dr. Gorman postulated that weeks or months would first have had to pass, making it highly likely that the "biological mechanisms of anti-NMDAR encephalitis were occurring weeks *before* 12/13/10." First Gorman Rep. at 7; *see also* Iizuka T, Yoshii S, Kan S, et al. *Reversible brain atrophy in anti-NMDA receptor encephalitis: a long-term observational study*, J. Neurol. 2010; 257:1686–1691, filed as Resp't's Ex. A Tab 5. Such articles, however, were vague in proposing a timeframe for development of ARE, and also involved small sample groups in

[25] These steps are 1) administration of the vaccine, 2) production of pro-inflammatory cytokines, 3) permeability of the blood brain barrier, 4) passive transfer of antibodies, 5) binding of the antibodies to the amino terminal domain, 6) internalization of the NMDA receptor away from the cell surface, and 7) synaptic dysfunction leading to abnormal neuronal function and subsequent neurological symptoms. First Gorman Rep. at 4-5.

which not all patients experienced brain atrophy. Iizuka at 1687. Indeed, ARE can occur without the presence of atrophy at all. *Dalmau* at 64 ("Brain MRI is unremarkable in 50% of patients").

Dr. Gorman further attempted to refute the Miller elements that Dr. Axelrod proposed had established a link between the HPV vaccine and R.B.'s ARE. First Gorman Rep. at 6. In particular, although Dr. Gorman accepted the ARE diagnosis for R.B.'s condition, he stated that a different trigger could have existed – in this case, an earlier URI – that was more consistent with the medical history. *Id*. at 5. In 70 percent of anti-NMDAR patients, symptoms from infection were present weeks prior to the encephalitis. *Id*., *see also Dalmau*. This explanation thus undercut the vaccine as explaining R.B.'s ARE.

Dr. Gorman then addressed the de-challenge theory proposed by Dr. Axelrod. Because improvement is common in ARE patients after treatment with IVIG and steroids (which R.B. received) "one cannot conclude that she improved [mainly] because she did not receive any further vaccines and/or more time elapsed from the vaccine." First Gorman Rep. at 5. Accordingly, the lack of "challenge" from further immunization was not meaningful.

Dr. Gorman's also took particular issue with Dr. Axelrod's suggested mechanism of molecular mimicry. In his first report, Dr. Gorman proposed that homology between certain HPV vaccine protein strains and myelin based protein was irrelevant, since ARE is not a demyelinating condition. First Gorman Rep. at 6. Rather, ARE is characterized by antibodies targeting a specific amino acid sequence in the amino terminal domain of the NMDA receptor protein (NR1), which he stated bears no homology to HPV16. *Id*. Dr. Gorman also attempted to refute Dr. Axelrod's alternative mechanism of epitope spreading (offered in reaction to criticism of molecular mimicry). Second Gorman Rep. at 3. In his view, there was no evidence that epitope spreading can instigate this kind of neurological injury, and even if there was reliable scientific evidence establishing a relationship between the HPV vaccine and ARE, the time that passed in this case between vaccination and injury was too short to establish such a reaction. *Id*.

Finally, Dr. Gorman proposed possible alternative causes for R.B.'s ARE, based upon his review of the medical records. He posited that R.B.'s reported URI three weeks prior to her vaccination could account for her condition, given that a prior infection was far more consistent with the actual timing of her symptoms than Petitioner's reading of the treatment history. *Id*. at 7. He also opined that R.B.'s history of alopecia areata, an autoimmune condition, could have predisposed her to ARE, since it was a secondary autoimmune condition that would occur after a prior such incident, although he did not cite literature or other scientific evidence linking the two. *Id*.

III. PROCEDURAL HISTORY

As noted above, the case was initiated in December 2013. After several delays in obtaining medical records, Petitioner filed her statement of completion on July 30, 2014. ECF No. 19. Not long after, in late August and early October, Ms. Al-Uffi filed her first expert report from Dr. Axelrod as well as Dr. Siegler's report.

On December 12, 2014, Respondent filed his Rule 4(c) report addressing his objections to the claim. ECF No. 26. That report also identified several missing medical records, and was filed along with the first expert report of Dr. Gorman. ECF Nos. 24-26. Petitioner attempted to file the remaining missing medical records on January 8, 2015, but found that there were still outstanding medical records requiring subpoena. In the meantime, on February 3, 2015, Petitioner filed Dr. Axelrod's second report and supporting medical literature. ECF Nos. 32-33.

On September 30, 2015, Petitioner requested in writing that I schedule a hearing on entitlement. ECF No. 54. The parties then began discussing convenient hearing dates, and I issued a pretrial order in December 2015 setting the entitlement hearing for November 17-18, 2016. ECF No. 61. In August 2016, however, the parties jointly indicated that they now preferred that the matter be resolved on the papers in lieu of hearing, and I therefore issued a revised order for briefing Petitioner's claim. *See* Order, dated August 15, 2016 (ECF No. 63).[26]

Petitioner filed her motion in support of her claim merely three days later. On October 28, 2016, Respondent filed his response. *See* Response for Judgment on the Administrative Record ("Response"), filed as ECF No. 68. Petitioner then filed a reply on November 7, 2016 as ECF No. 70.[27] This matter is now ripe for a decision.

IV. THE PARTIES' RESPECTIVE ARGUMENTS

Petitioner's motion asserts that she has carried her burden of proof, based upon the theory that R.B. suffered a secondary immune response causing her to develop ARE shortly after receiving the final dose of the HPV vaccine. *See* Mot. at 8. In so arguing, Petitioner relies most heavily on the eight elements established by Miller. *Id*. at 8-10. Petitioner also offers epitope spreading as the

[26] In this case, the parties specifically requested that I decide this case on the papers. The Vaccine Act and Rules not only contemplate but encourage special masters to decide petitions in this manner rather than via evidentiary hearing, where (in the exercise of their discretion) they conclude that the former means of adjudication will properly and fairly resolve the case. Section 12(d)(2)(D); Vaccine Rule 8(d). The choice to do so has been affirmed on appeal. *See Hooker v. Sec'y of Health & Human Servs.,* No. 02-472V, 2016 WL 3456435, at *21 n.19 (Fed. Cl. Spec. Mstr. May 19, 2016) (citing *Hovey v. Sec'y of Health & Human Servs.*, 38. Fed. Cl. 397, 397 (1997)).

[27] Respondent also filed a sur-reply in this action. Sur-Reply, dated November 16, 2016 (ECF No. 72). That document, however, was intended solely to address the Petitioner's attacks on Dr. Gorman's qualifications, and otherwise made no substantive points regarding the merits of the present claim.

biological mechanism by which the vaccine caused the ARE, largely abandoning Dr. Axelrod's initial proposal that molecular mimicry was an applicable mechanism. *Id.* at 9.

Petitioner attempted to rebut what Respondent's expert opined was the "fatal flaw" of Petitioner's case—the timing of onset. Although Petitioner conceded that the medical records were inconsistent regarding when R.B.'s most alarming symptoms of behavior change began, she argued that the greater weight of the evidence supported a finding of onset on December 10, 2010. Mot. at 14. She also rejected Respondent's contention that the minimum time needed for a reaction was five days, relying on Dr. Axelrod's opinion of the short time it would take for a secondary immune response to occur. She attempted to bulwark this argument by referencing Dr. Siegler's opinion about the relationship between vaccine and injury.

In opposing the motion, Respondent reasserted Dr. Gorman's argument that R.B. displayed ARE-like symptoms (as manifested in her behavioral problems) prior to receiving the HPV vaccine. *See* Response at 13. Respondent cited to various points in the medical records when R.B. was said to have exhibited behavior more egregious than that typically associated with teenagers. *Id*. Alternatively, Respondent argued that onset on the 8th or even the 10th of December was too soon for the processes suggested by Dr. Axelrod to occur. *Id*. at 22. Respondent did not, however, squarely address Dr. Axelrod's theory that R.B.'s ARE was instigated by a secondary immune response. Respondent also dismissed Petitioner's theory of homology as irrelevant to this case, instead arguing that the antibody implicated by ARE would not likely be produced by an autoimmune reaction involving any of the HPV components. *Id*. at 19.

On reply, Ms. Al-Uffi pointed out that much of Respondent's own medical literature suggested that a reaction to the HPV vaccine could in fact occur as soon as the same day of vaccination. *See* Reply at 4-5. The remainder of the reply brief focused on defending the expertise of Drs. Axelrod and Siegler. *Id.* at 8.[28]

V. APPLICABLE LEGAL STANDARDS

A. Petitioner's Overall Burden in Vaccine Program Cases

To receive compensation in the Vaccine Program, a petitioner must prove either: (1) that she suffered a "Table Injury" – *i.e.*, an injury falling within the Vaccine Injury Table – corresponding to one of the vaccinations in question within a statutorily prescribed period of time

[28] Both parties devoted more than a little briefing space to attacking their adversary's expert's credentials while defending their own (with Respondent going so far as to file a surreply intended to rehabilitate Dr. Gorman's expertise). *See* Sur-Reply at 1-4. These efforts were somewhat wasted. Thus, Petitioner's attacks against Dr. Gorman missed the mark, given his clear expertise to offer opinions relevant to ARE; indeed, he was the most qualified expert to offer an opinion in this case (at least with respect to the disease at issue). But my decision does not turn on how credible each expert was in light of his professional qualifications, and accordingly there was no need for the parties to crow in favor of their chosen expert.

or, in the alternative, (2) that her illnesses were actually caused by a vaccine (a "Non-Table Injury"). *See* Sections 13(a)(1)(A), 11(c)(1), and 14(a), as amended by 42 C.F.R. § 100.3; § 11(c)(1)(C)(ii)(I); *see also Moberly v. Sec'y of Health & Human Servs*., 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Capizzano v. Sec'y of Health & Human Servs*., 440 F.3d 1317, 1320 (Fed. Cir. 2006).[29] In this case, Petitioner does not assert a Table claim.

For both Table and Non-Table claims, Vaccine Program petitioners bear a "preponderance of the evidence" burden of proof. Section 13(1)(a). That is, a petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." *Moberly*, 592 F.3d at 1322 n.2; *see also Snowbank Enter. v. United States*, 6 Cl. Ct. 476, 486 (1984) (mere conjecture or speculation is insufficient under a preponderance standard). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Human Servs*., 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, a petitioner must demonstrate that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly*, 592 F.3d at 1321 (quoting *Shyface v. Sec'y of Health & Human Servs*., 165 F.3d 1344, 1352-53 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health & Human Servs*., 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner may not receive a Vaccine Program award based solely on her assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. Section 13(a)(1).

In attempting to establish entitlement to a Vaccine Program award of compensation for a Non-Table claim, a petitioner must satisfy all three of the elements established by the Federal Circuit in *Althen v. Sec'y of Health & Human Servs.,* 418 F.3d 1274, 1278 (Fed. Cir. 2005) "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." *Althen*, 418 F.3d at 1278.

Each of the *Althen* prongs requires a different showing. Under *Althen* prong one, petitioners must provide a "reputable medical theory," demonstrating that the vaccine received *can cause* the type of injury alleged. *Pafford*, 451 F.3d at 1355-56 (citations omitted). To satisfy this prong, a petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Human Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). Such a theory must only be "legally probable, not medically or scientifically certain." *Id*. at 549.

[29] Decisions of special masters (some of which I reference in this ruling) constitute persuasive but not binding authority. *Hanlon v. Sec'y of Health & Human Servs.*, 40 Fed. Cl. 625, 630 (1998). By contrast, Federal Circuit rulings concerning legal issues are binding on special masters. *Guillory v. Sec'y of Health & Human Servs.*, 59 Fed. Cl. 121, 124 (2003), *aff'd*, 104 F. App'x 712 (Fed. Cir. 2004); *see also Spooner v. Sec'y of Health & Human Servs.*, No. 13-159V, 2014 WL 504728, at *7 n.12 (Fed. Cl. Spec. Mstr. Jan. 16, 2014).

Petitioners may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1378-79 (Fed. Cir. 2009) (citing *Capizzano*, 440 F.3d at 1325-26). Special masters, despite their expertise, are not empowered by statute to conclusively resolve what are essentially thorny scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed "not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." *Id.* at 1380. Accordingly, special masters must take care not to increase the burden placed on petitioners in offering a scientific theory linking vaccine to injury. *See, e.g., Contreras v. Sec'y of Health & Human Servs.*, 121 Fed. Cl. 230, 245 (2015) ("[p]lausibility . . . in many cases *may* be enough to satisfy *Althen* prong one" (emphasis in original)), *reversed on other grounds*, 844 F.3d 1363 (Fed. Cir. 2017). But this does not negate or reduce a petitioner's ultimate burden to establish her overall entitlement to damages by preponderant evidence. *W.C. v. Sec'y of Health & Human Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted).

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375-77; *Capizzano*, 440 F.3d at 1326; *Grant v. Sec'y of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). In establishing that a vaccine "did cause" injury, the opinions and views of the injured party's treating physicians are entitled to some weight. *Andreu*, 569 F.3d at 1367; *Capizzano*, 440 F.3d at 1326 ("medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause and effect show[s] that the vaccination was the reason for the injury'") (quoting *Althen*, 418 F.3d at 1280). Medical records are generally viewed as particularly trustworthy evidence, since they are created contemporaneously with the treatment of the patient. *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

However, medical records and/or statements of a treating physician's views do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. Section 13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"); *Snyder v. Sec'y of Health & Human Servs.*, 88 Fed. Cl. 706, 746 n.67 (2009) ("there is nothing . . . that mandates that the testimony of a treating physician is sacrosanct – that it must be accepted in its entirety and cannot be rebutted"). As with expert testimony offered to establish a theory of causation, the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases. The views of treating physicians should also be weighed against other, contrary evidence also present in the record – including conflicting opinions among such individuals. *Hibbard v. Sec'y of Health & Human Servs.*, 100 Fed. Cl. 742, 749 (2011) (not arbitrary or capricious for special master to weigh competing treating physicians' conclusions

against each other), *aff'd*, 698 F.3d 1355 (Fed. Cir. 2012); *Caves v. Sec'y of Dep't of Health & Human Servs.*, 100 Fed. Cl. 119, 136 (2011), *aff'd*, 463 F. App'x 932 (Fed. Cir. 2012); *Veryzer v. Sec'y of Health & Human Servs.*, No. 06-522V, 2011 WL 1935813, at *17 (Fed. Cl. Spec. Mstr. Apr. 29, 2011), *mot. for review den'd*, 100 Fed. Cl. 344, 356 (2011), *aff'd without opinion*, 475 Fed. App'x 765 (Fed. Cir. 2012).

The third *Althen* prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase "medically-acceptable temporal relationship." *Id.* A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *Bazan v. Sec'y of Health & Human Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must also coincide with the theory of how the relevant vaccine can cause an injury (*Althen* prong one's requirement). *Id*. at 1352; *Shapiro v. Sec'y of Health & Human Servs.*, 101 Fed. Cl. 532, 542 (2011), *recons. den'd after remand*, 105 Fed. Cl. 353 (2012), *aff'd mem.*, 2013 WL 1896173 (Fed. Cir. 2013); *Koehn v. Sec'y of Health & Human Servs.*, No. 11-355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for review den'd* (Fed. Cl. Dec. 3, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

B. Law Governing Analysis of Fact Evidence

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records. Section 11(c)(2). The special master is required to consider "all [] relevant medical and scientific evidence contained in the record," including "any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death," as well as "the results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." Section 13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Human Servs*., 3 F.3d 415, 417 (Fed. Cir. 1993) (it is within the special master's discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such a determination is evidenced by a rational determination).

Medical records that are created contemporaneously with the events they describe are presumed to be accurate and "complete" (*i.e.*, presenting all relevant information on a patient's health problems). *Cucuras*, 993 F.2d at 1528; *Doe/70 v. Sec'y of Health & Human Servs.*, 95 Fed. Cl. 598, 608 (2010) ("[g]iven the inconsistencies between petitioner's testimony and his

contemporaneous medical records, the special master's decision to rely on petitioner's medical records was rational and consistent with applicable law"), *aff'd*, *Rickett v. Sec'y of Health & Human Servs*., 468 F. App'x 952 (Fed. Cir. 2011) (non-precedential opinion). This presumption is based on the linked propositions that (i) sick people visit medical professionals; (ii) sick people honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec'y of Health & Human Servs*., No. 11-685V, 2013 WL 1880825, at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013); *Cucuras v. Sec'y of Health & Human Servs*., 26 Cl. Ct. 537, 543 (1992), *aff'd*, 993 F.2d 1525 (Fed. Cir. 1993) ("[i]t strains reason to conclude that petitioners would fail to accurately report the onset of their daughter's symptoms. It is equally unlikely that pediatric neurologists, who are trained in taking medical histories concerning the onset of neurologically significant symptoms, would consistently but erroneously report the onset of seizures a week after they in fact occurred").

Accordingly, if the medical records are clear, consistent, and complete, then they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Human Servs*., No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). Indeed, contemporaneously medical records are generally found to be deserving of greater evidentiary weight than oral testimony – especially where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; *see also Murphy v. Sec'y of Health & Human Servs.*, 23 Cl. Ct. 726, 733 (1991), *aff'd*, 968 F.2d 1226 (Fed. Cir.), *cert. den'd*, *Murphy v. Sullivan*, 506 U.S. 974 (1992) (citing *United States v. United States Gypsum Co.*, 333 U.S. 364, 396 (1947) ("[i]t has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.")).

However, there are situations in which compelling oral testimony may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Campbell v. Sec'y of Health & Human Servs*., 69 Fed. Cl. 775, 779 (2006) ("like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking"); *Lowrie*, 2005 WL 6117475, at *19 ("[w]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent") (quoting *Murphy v. Sec'y of Health & Human Servs.*, 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed. Cir. 1992)). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. *Andreu*, 569 F.3d at 1379; *Bradley v. Sec'y of Health & Human Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

C. Analysis of Expert Testimony

Establishing a sound and reliable medical theory often requires a petitioner to present expert testimony in support of his claim. *Lampe v. Sec'y of Health & Human Servs.*, 219 F.3d 1357, 1361 (Fed. Cir. 2000). Vaccine Program expert testimony is usually evaluated according to the factors for analyzing scientific reliability set forth in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 594-96 (1993). *See Cedillo v. Sec'y of Health & Human Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010) (citing *Terran v. Sec'y of Health & Human Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999)). "The *Daubert* factors for analyzing the reliability of testimony are: (1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community." *Terran*, 195 F.3d at 1316 n.2 (citing *Daubert*, 509 U.S. at 592-95).

The *Daubert* factors play a slightly different role in Vaccine Program cases than they do when applied in other federal judicial fora (such as the district courts). *Daubert* factors are usually employed by judges (in the performance of their evidentiary gatekeeper roles) to exclude evidence that is unreliable and/or could confuse a jury. In Vaccine Program cases, by contrast, these factors are used in the *weighing* of the reliability of scientific evidence proffered. *Davis v. Sec'y of Health & Human Servs.*, 94 Fed. Cl. 53, 66-67 (2010) ("uniquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted"). The flexible use of the *Daubert* factors to evaluate the persuasiveness and reliability of expert testimony has routinely been upheld. *See, e.g.*, *Snyder*, 88 Fed. Cl. at 742-45. In this matter (as in numerous other Vaccine Program cases), *Daubert* has not been employed at the threshold, to determine what evidence should be admitted, but instead to determine whether expert testimony offered is reliable and/or persuasive.

Respondent frequently offers one or more experts of her own in order to rebut a petitioner's case. Where both sides offer expert testimony, a special master's decision may be "based on the credibility of the experts and the relative persuasiveness of their competing theories." *Broekelschen v. Sec'y of Health & Human Servs.*, 618 F.3d 1339, 1347 (Fed. Cir. 2010) (citing *Lampe*, 219 F.3d at 1362). However, nothing requires the acceptance of an expert's conclusion "connected to existing data only by the *ipse dixit* of the expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." *Snyder*, 88 Fed. Cl. at 743 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 146 (1997)); *see also Isaac v. Sec'y of Health & Human Servs.*, No. 08-601V, 2012 WL 3609993, at *17 (Fed. Cl. Spec. Mstr. July 30, 2012), *mot. for review den'd*, 108 Fed. Cl. 743 (2013), *aff'd*, 540 Fed. App'x 999 (Fed. Cir. 2013) (citing *Cedillo*, 617 F.3d at 1339).

Weighing the relative persuasiveness of competing expert testimony, based on a particular expert's credibility, is part of the overall reliability analysis to which special masters must subject expert testimony in Vaccine Program cases. *Moberly*, 592 F.3d at 1325-26 ("[a]ssessments as to the reliability of expert testimony often turn on credibility determinations"); *see also Porter v. Sec'y of Health & Human Servs*., 663 F.3d 1242, 1250 (Fed. Cir. 2011) ("this court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act"). It is in the exercise of my duties as a special master to weigh competing expert testimony. *Copenhaver v. Sec'y of Health & Human Servs.*, No. 13-1002V, 2016 WL 6947389, at *5 (Fed. Cl. Oct. 20, 2016) ("Special Masters may use their discretion in weighing expert testimony, and case law supports that discretion").

D. Consideration of Medical Literature

Both parties filed medical and scientific literature in this case, including some articles (such as those discussing molecular mimicry and protein sequences in vaccines) that do not factor into the outcome of this decision. I have reviewed all of the medical literature submitted in this case, but I only discuss those articles that are most relevant to my determination and/or are central to Petitioner's case – just as I have not exhaustively discussed every individual medical record filed. *Moriarty v. Sec'y of Health & Human Servs.*, No. 2015-5072, 2016 WL 1358616, at *5 (Fed. Cir. Apr. 6, 2016) ("[w]e generally presume that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision") (citation omitted); *see also Paterek v. v. Sec'y of Health & Human Servs.,* 527 F. App'x 875, 884 (Fed. Cir. 2013) ("[f]inding certain information not relevant does not lead to — and likely undermines — the conclusion that it was not considered").

VI. ANALYSIS

A. Anti-NMDAR Encephalitis

As was mentioned above, there is no dispute that R.B. was found to possess the NMDA receptor antibodies associated with ARE, and that this was her proper diagnosis. ARE is an autoimmune neurological condition occurring when a patient possesses antibodies to the N-methyl D-aspartate[30] receptor that interfere with that receptor's function. Resp't's Ex. Tab 2 at 1. The condition was first discovered around 2005 and is characterized by a host of clinical problems. Notably, it is often first recognized with the onset of psychiatric symptoms, such as angry or

[30] N-methyl-d-aspartate is a neurotransmitter similar to glutamate, found in the central nervous system. *Dorland's* at 1152.

aggressive outbursts, memory loss, seizures, agitation, and abnormal movements. *Id*. at 1-2. Examination of patients with this condition often reveals encephalopathy in various regions of the brain—subcortical structures, limbic regions, amygdalae, and frontostriatal circuitry. *Id*. The conclusive test for the condition is the presence of antibodies in the serum and cerebrospinal fluid (CSF). The condition is most common in women and is more frequently recognized in young teenagers and children. *Id*. at 3.

B. *Althen* Prong One

As reviewed above, the law governing resolution of Vaccine Program claims does not require petitioners to present a medically certain theory. Instead, they merely need establish a "legally probable" theory – and may do so, moreover, without offering direct proof linking the vaccine to the disease at issue, or large-scale epidemiologic studies establishing the vaccine's risk to potentially cause the illness. *Andreu*, 569 F.3d at 1378-79. Thus, even though Ms. Al-Uffi lacks this type of direct evidence, this alone is not a basis for finding that she has not satisfied the first *Althen* prong.

Dr. Axelrod presented the theory that the HPV vaccine could cause an autoimmune condition like ARE. That theory has been accepted when applied in the same context, and to the HPV vaccine as well. *See, e.g., McCulloch v. Sec'y of Health and Human Services*, No. 09-293, 2015 WL 3640610 (Fed. Cl. Spec. Mstr. May 22, 2015). In *McCulloch*, Special Master Gowen found that a petitioner had presented a persuasive medical theory that autoimmune limbic encephalitis was more likely than not caused by the HPV vaccine Petitioner received when she was twelve. Accordingly, the theory itself offered in this case does not, at its face value, propose something that is completely novel.

Although Petitioner's experts could not provide any studies linking the HPV vaccine with ARE, Dr. Siegler did offer Hofmann, a case study in which a young female developed ARE within 24 hours of receipt of the TdaP and the polio vaccines. Hofmann at 1. Individual case studies are not themselves particularly probative in the context of establishing the first *Althen* prong (especially where they involve a totally different vaccine), but often have some evidentiary value – especially when dealing with a condition that is itself not yet the subject of extensive research (a fact that can explain a claimant's inability to offer scientific studies in support of the theory).

Petitioner proposed two interrelated biological mechanisms by which the HPV vaccine could cause ARE. The first such mechanism – impairment of the blood-brain barrier due to cytokine production encouraged by the vaccine – was not meaningfully challenged by Respondent's expert, although he questioned whether it could occur in a short timeframe. First Gorman Rep. at 5 ("theoretically one can construct a sequence of events by which vaccination

leads to impairment of the blood brain barrier function"). Impairment of the blood-brain barrier is significant because it can allow for foreign antigens, like those contained in a vaccine, to enter the brain. Once those antigens cross the blood-brain barrier into the brain, Petitioner's secondary biological mechanism comes into play.

Petitioner altered her proposed second mechanism in response to Dr. Gorman's criticisms. Initially, Dr. Axelrod proposed molecular mimicry based on putative homology between components of the HPV vaccine and brain proteins. But Dr. Gorman strongly, and effectively, contested this assumption, given the HPV vaccine's formula plus the nature of ARE, which is not a demyelinating condition. First Gorman Rep. at 6. Dr. Axelrod subsequently revised his theory somewhat, proposing the alternative mechanism of epitope spreading. *Id*. In response, Dr. Gorman observed that it lacked any support in the literature when applied in this context. Second Gorman Rep. at 3.

Respondent has raised legitimate questions about Petitioner's theory that her experts did not defend with total success. However, such challenges must be viewed in the context of relevant Program case law. Epitope spreading has been accepted in other Vaccine Program cases as a mechanistic framework for explaining how an autoimmune process instigated by a vaccine could cause injury, and thus has some reliability. *See, e.g., Althen,* 58 Fed. Cl. 270 at 285-86. Moreover, Dr. Gorman's observations that this mechanism was not supported by sufficient specific scientific literature does not amount to a rebuttal of the theory. *Campbell v. Sec'y of Health & Human Servs.,* 97 Fed. Cl. 650, 662 (2011) ("[a] claimant's presentation through expert testimony of a biological theory of causation connecting the vaccine to the injury which the government does not successfully rebut advances the claimant's case"). And most significantly, Program petitioners are not in fact required to establish a biological mechanism explaining the precise manner, in molecular detail, for how a vaccine could cause a particular disease - because to require such a specific level of proof is inconsistent with the Program's goals. *Knudsen*, 35 F3d. 543, 548-49. Thus, although Dr. Axelrod has not proven that his proposed mechanism could occur in connection with the HPV vaccine, he need not have done so in the first place.

In addition, Dr. Axelrod's theory is backstopped by the opinion of Dr. Siegler, a pediatric neurologist, and one of R.B.'s treaters both at the outset of her hospitalization and then long after. As I have observed in other cases, a treater's opinion (while typically offered in support of the second *Althen* prong) can have evidentiary value in establishing a causation theory. *See Gerhardt v. Sec'y of Health & Human Servs.*, No. 9-180V, 2014 WL 4712690, at *10 (Fed. Cl. Spec. Mstr. Aug. 29, 2014), *citing Caves v. Sec'y of Health & Human Servs.*, 100 Fed. Cl. 119, 145 (2011), *aff'd*, 463 Fed. App'x 932 (Fed. Cir. 2012) (although there is an "analytical demarcation" between the analysis of *Althen* prongs one and two evidence, a treating physician's "statement that a vaccine did in fact cause an injury presupposes that the vaccine is capable of causing that injury"). This is

true even where, as here, the treater does not himself offer a scientific explanation for how a vaccine caused a condition.

Overall, Petitioner's proposed causation theory is not particularly robust, but it has just enough validity and reliability from a legal standpoint to meet the relatively-lenient preponderance standard that is applied in Program cases. I thus find that Petitioner has met this first prong.

C. *Althen* Prongs Two and Three

I shall combine my discussion of the two remaining prongs given their overlap. To summarize from above, *Althen* prong two requires that Petitioner establish a logical explanation of how the vaccine caused an injury to the Petitioner, while prong three requires proof of a medically acceptable temporal relationship between vaccination and injury. Here, these two issues are intertwined, because Respondent's consistent attack against Petitioner's case arises from his contention that R.B.'s psychiatric/behavioral symptoms occurred too soon after (if not before) vaccination to be caused by the vaccine, given what would be considered medically acceptable.

1. Onset - When did R.B. first begin to show symptoms?

The parties agree that the records do not allow for an easy onset determination, and I fully concur. The medical histories provided by Ms. Al-Uffi often contradict each other, variously placing onset of the most severe of R.B.'s symptoms as right before, the day of, or a couple days after vaccination. *See e.g.*, Pet'r's Exs. 4, 7, 21, and 22. Because of the general presumption of the accuracy of medical records in Program cases (and the statements they contain that are given to treaters, ostensibly with the intention of accurately conveying to treaters a sick person's condition), contrary statements about the start of R.B.'s most alarming psychiatric or behavioral symptoms cannot be readily harmonized simply from review of the records.

However, there are a number of indisputable facts that can be assessed independent of what Petitioner told treaters (or what those treaters heard). They include the following: (a) R.B. had been receiving psychological counseling long before the December 2010 vaccination, but (b) her symptoms became so acute and alarming to Ms. Al-Uffi, in the days following the vaccination, that Petitioner repeatedly sought help for R.B. from *three* separate treaters (Ms. Yankovich, Shadow Mountain, and Parkside), and (c) eventually took R.B. to St. Francis Hospital once these initial treatment efforts had not provided her with the degree of assistance she felt the circumstances mandated. It is also undisputed that the symptoms R.B. displayed during this time could be associated with ARE, and that the ultimate ARE diagnosis was correct.

Given the above, there is sufficient preponderant evidence for the conclusion that onset of R.B.'s most severe and self-evident behavioral changes began two to three days after the December 8, 2010 vaccination. It is reasonable to conclude that Petitioner's heightened, and growing, concern about the nature of R.B.'s demonstrated behaviors led her first to seek the input of a number of psychiatric-type treaters before opting (at Ms. Yankovich's recommendation) for more traditional medical care – and that her focused and comprehensive search for care was a function of her concern about the alarming character of R.B.'s behavior. I can thus distinguish the reports of these behaviors (which Ms. Al-Uffi termed new over the prior 24 hours on December 10th at Parkside) from R.B.'s prior behavioral problems, which by comparison seem more reflective of teenage misbehavior or anger than evidence of increasingly severe neurologic damage. Respondent for his part has not established that R.B.'s earlier behavior for which she received counseling is comparable, or reflects conduct on a continuum leading to the more uncommon behaviors reported in this case after R.B.'s hospitalization (lip-smacking, speaking in Spanish, memory lapse, etc.).

2. Secondary Immune Response

Applying the above, I find that Petitioner has established a logical sequence of events between R.B.'s development of ARE and her receipt of the HPV vaccine. In particular, she has done so through her theory of a secondary immune response, which (as Dr. Axelrod explained) occurs when the immune system is exposed to a foreign antigen for the second or third time, resulting in a faster reaction than what would be associated with the initial immune response. First Axelrod Rep. at 1. R.B.'s immune system had already encountered the foreign HPV proteins twice before, allowing her cells to achieve immunologic memory. *Id.* Thus, the more rapid onset of R.B.'s initial symptoms (in the days after the December 8, 2010 vaccination) would be consistent with such a secondary response.

Dr. Gorman did not focus on this element of Petitioner's case, including only a small paragraph in his first report addressing the possibility of a secondary immune response. First Gorman Rep. at 4. He did, however, cite to the Institute of Medicine ("IOM"), which almost confirms the propositions made by Dr. Axelrod stating that "[d]ue to the development of memory B and T cells during the primary immune response, the latency between subsequent exposure to the antigen and development of the immune response will usually be shorter. The lag phase is generally 1 to 3 days; the logarithmic phase of the secondary antibody response occurs over the next 3 to 5 days." *See* IOM 2012, *Adverse effects of vaccines: evidence and causality*, Washington, DC: The National Academies Press, at 58. That timeframe is consistent with my onset finding, and therefore corroborates rather than contradicts Petitioner's theory.[31]

[31] Dr. Gorman also raised intriguing points about brain tissue reduction seen on CT scans and MRIs for R.B. – a process which would biologically take considerable time to develop, and therefore rebutted a fast onset for R.B.'s ARE. First Gorman Rep. at 7. But the literature Respondent cited in support did not state that such brain abnormalities

3. Additional Factors Supporting Second Althen Prong

I also find support for a logical sequence of events for R.B.'s condition in the narrative of R.B's treating physician, Dr. Siegler. The Program recognizes that treating physicians are in a good position to opine that a vaccination was the reason for injury. *Capizzano*, 440 F.3d at 1326. Here, although Dr. Siegler was not the first treater to diagnose R.B. with ARE, he had provided treatment to R.B. since the beginning of her onset, and his report demonstrated awareness of her clinical progression. In particular, Dr. Siegler's treatment notes show also that he was engaged in an inquiring effort to identify the cause and nature of R.B.'s symptoms. Thus, his differential diagnosis initially included alternative explanations for R.B.'s condition, such as post-infectious encephalopathy, but Dr. Siegler discarded them when they could not be corroborated. Pet'r's Ex. 4 at 22. Such contemporaneous records are particularly probative. *Cucuras*, 993 F.2d 1525, 1528 (Fed. Cir. 1993) ("The [medical] records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events"). Accordingly, Dr. Siegler's view – having treated R.B. at the start of her hospitalization, having had the opportunity to consider alternative explanations, but having been unable to find one that had evidentiary support – that the HPV vaccine was the remaining, most likely explanation for Petitioner's condition is entitled to additional weight herein, and it favors Petitioner's claim.

D. Alternative Causation

Because I find that Petitioner has established her *prima facie* case by a preponderance of the evidence, the burden now shifts to Respondent to prove by a preponderance of the evidence an alternative, unrelated cause for R.B.'s condition. *Heinzelman v. Sec'y of Health & Human Servs.*, No. 07-01V, 2008 WL 5479123, at *7 (Fed. Cl. Spec. Mstr. Dec. 11, 2008)("[o]nce…causation is established, the petitioner is entitled to compensation unless the government can show by a preponderance of the evidence that the injury is due to factors unrelated to the vaccine, i.e., an alternative cause"). Although Respondent did not actively attempt to meet this burden, I do not find that he could have done so based upon this record – since it lacks sufficient preponderant evidence of possible alternative causes for R.B.'s ARE.

As the record reveals, R.B. presented to the ER with no evidence of fever, headache, or other sign of infection – any of which might support the possibility that her reported earlier URI was to blame rather than the vaccine. The only evidence of a prior infection was in Petitioner's

were always associated with ARE, nor did Respondent reference medical record evidence suggesting that treaters later identified this as suggestive of a process that predated the December 2010 HPV dose.

recollection at R.B.'s initial treatment that she had experienced a URI three weeks before. However, R.B. subsequently underwent extensive testing that was negative for an existing or past infection, leading her treaters to abandon hypotheses of prior infections, while conclusively establishing that R.B. possessed NMDAR antibodies. *See generally* Pet'r's Ex. 2. Thus, even if I accepted Dr. Gorman's assertion that patients with ARE more often than not possess some antecedent infection like a URI, I do not find that there is preponderant evidence proving *in this case* that R.B. had such an infection. Accordingly, Respondent has not established an alternative cause by a preponderance of the evidence.

VII. CONCLUSION

Petitioner's claim presents a close case. Her causation theory is thin in many respects, and there are reasonable questions regarding the onset of R.B.'s ARE-related symptoms, both due to the contradictory reports in the medical records as well as R.B.'s earlier medical history. In other cases with different facts, such matters could prove fatal to the claim. However, I am cognizant of the fact that "close calls regarding causation are resolved in favor of injured claimants." *Andreu*, 569 F.3d at 1378. This matter should similarly be resolved.

Accordingly, I find that Petitioner has established her *prima facie* case by proving by a preponderance of the evidence for each of the *Althen* prongs. Petitioner has successfully proven a persuasive medical theory, a logical explanation of cause and effect, and a medically appropriate temporal relationship between vaccination and injury. Respondent has failed to carry her burden in establishing an alternative, unrelated cause for R.B.'s condition. **Petitioner is therefore entitled to compensation under the Vaccine Program.**

In order to guide the parties through the damages phase of the action, a separate damages order will issue.

IT IS SO ORDERED.

s/Brian H. Corcoran
Brian H. Corcoran
Special Master